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CORPATH-PRECISE: FINAL RESULTS OF THE FIRST PIVOTAL STUDY FOR ROBOTICALLY-ENHANCED PCI

i2 Oral Contributions
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Background: The current practice of percutaneous coronary intervention (PCI) is fraught with technical inconsistencies that impose risks for both patient (complications, radiation, contrast media) and operator (spine strain and radiation exposure). Robotically-assisted PCI has the potential to improve technical precision, and to decrease radiation exposure, orthopedic injury, and contrast media volume. We report the first pivotal multicenter study investigating the safety and efficacy of a novel vascular robotic system for coronary PCI.

Methods: Total of 163 patients were enrolled in a single arm, open label, prospective, multi-center study. All had evidence of myocardial ischemia, and significant stenosis in a native coronary artery. All PCIs were done with the CorPath 200 System (Corindus, Natick, MA). This vascular robotic system consists of two units. The bedside unit includes of a cassette mounted on a robotic drive that advances, retracts, and rotates off-the-shelf 0.014" guidewires and rapid exchange PCI catheter systems. The operator manipulates the interventional devices from a control console with joysticks while sitting comfortably remote from the patient, in the radiation-shielded interventional cockpit. Patients were followed for 30 days. The primary endpoint is procedural success, defined as less than 30% residual stenosis (core-lab QCA) at the completion of the interventional procedure in the absence of Major Adverse Cardiovascular Event (MACE, defined as composite of death, myocardial infarction, or clinically driven target vessel revascularization). Device technical success is defined as the successful advancement and retraction of the PCI devices using the CorPath 200 System without conversion to manual operation.

Results and Conclusions: At presentation, we will have completed enrollment, including complete 30 days follow-up. The final results of the first pivotal remote-control robotic PCI system will be presented with full core-lab and adjudicated data.